

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION

UNITED STATES OF AMERICA	§	
	§	
v.	§	Criminal No. 3:15-CR-496-L
	§	
USPLABS, LLC (01)	§	
JACOBO GEISLER (02)	§	
JONATHAN DOYLE (03)	§	
MATTHEW HEBERT (04)	§	
KENNETH MILES (05)	§	
S.K. LABORATORIES, INC. (06)	§	
SITESH PATEL (07)	§	
CYRIL WILLSON (08)	§	

**MEMORANDUM OPINION AND ORDER  
ACCEPTING IN PART AND REJECTING IN PART  
FINDINGS AND RECOMMENDATIONS OF THE MAGISTRATE JUDGE**

Before the court are:

1. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc., and Sitesh Patel's Motion to Dismiss Count Ten (Doc. 220);
2. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles' Motion to Dismiss Counts Nine and Ten for Unconstitutional Vagueness (Doc. 221);
3. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Counts Two Through Four of the First Superseding Indictment as Untimely (Doc. 293);
4. Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Cyril Willson's Motion to Dismiss Count 7 (Doc. 379);
5. Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles' Joint Motion to Dismiss Counts 5, 8, and 9 (Doc. 383);

6. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Count 6 (Doc. 387);

7. Defendant Kenneth Miles' Motion to Dismiss Count Nine and Ten (Doc. 392); and

8. Defendant Cyril Willson's Motion to Dismiss Count 5 and Motion to Adopt In-Part Codefendants' Motion to Dismiss Counts 5, 8, 9 (Doc. 394).

(sometimes collectively, "Defendants' Motions to Dismiss"). Pursuant to 28 U.S.C. § 636 (b)(1)(B), the court referred Defendants' Motions to Dismiss to United States Magistrate Judge Renée Harris Toliver for findings and recommendation. *See* Order of Reference (Doc. 343); Order of Reference (Doc. 436). On June 13, 2018, Magistrate Judge Toliver submitted her Amended Findings, Conclusions, and Recommendation of the United States Magistrate Judge (Doc. 477) ("Report"). Defendants and the Government have filed objections to the Report. *See* Docs. 478, 480, 482, 483, 485, and 488. After careful consideration of the objections, record, and applicable law, and having conducted a de novo review of those portions of the Report to which objections were made, the court, for the reasons that follow, **overrules** Defendants' objections, **sustains** the Government's objection, and **accepts in part** and **rejects in part** the Report.

## **I. Factual Background**

### **A. The Defendants**

Defendants are USPlabs, LLC ("USPlabs"), a dietary supplement own-label distributor based in Dallas, Texas; S.K. Laboratories, Inc. ("S.K. Labs"), a California corporation that manufactured USPlabs' supplements and consulted on supplement formulation; Jacobo Geissler ("Geissler"), a co-founder, co-owner, and chief executive officer of USPlabs; Jonathan Doyle ("Doyle"), a co-founder, co-owner, and president of USPlabs; Matthew Hebert ("Hebert"), a co-owner of USPlabs responsible for product packaging design; Cyril Willson ("Willson"), also known as "Erik White," a consultant

to USPlabs, formerly a co-owner; Kenneth Miles (“Miles”), USPlabs’ compliance officer; and Sitesh Patel (“Patel”), a vice-president and employee of S.K. Labs.

## **B. The Indictment**

On January 5, 2016, the Government filed an 11-Count Superseding Indictment (“the Indictment”) (Doc. 95) against Defendants. The charges in the Indictment stem from Defendant USPlabs’ sale of dietary/weight loss supplements, which were manufactured by Defendant S.K. Labs. Doc. 95 at 5-6. The Indictment generally alleges that Defendants conspired to import and sell synthetic dietary supplements, but falsely marketed the products as plant-based under the theory that federal regulatory agencies would be less likely to question the importation of plant extracts, and retailers would be more likely to sell such products. Doc. 95 at 6. The Indictment further alleges that, during the conspiracy, certain Defendants created false documentation to import a synthetic substance—1,3-dimethylamylamine, known as DMAA—which they represented was a geranium plant extract. According to the Indictment, certain Defendants then used the DMAA in some of their supplements, which thereafter became best-selling products. Doc. 95 at 7, 14-15.

It is further alleged that when DMAA became the subject of controversy in the dietary supplement industry, USPlabs, through Defendant Geissler, began importing other chemicals under false labels to determine if they could be used in new dietary supplements. Doc. 95 at 9. Two such ingredients were aegeline, a synthetic version of an extract from a tree native to India, and the pulverized roots of a Chinese herb, *cynanchum auriculatum* (“CA”), both of which USPlabs is alleged to have purchased from China using fake certificates of analysis (“COA”).<sup>1</sup> The first

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<sup>1</sup> The Food and Drug Administration defines a COA as “a document, provided by the supplier of a component prior to or upon receipt of the component, that documents certain characteristics and attributes of the component.” Guidance for Industry Current Good Manufacturing Practice in Manufacturing,

aegeline-containing version of one of Defendants’ supplements was OxyElite Pro “New Formula” (“OEP-NF”). Doc. 95 at 9-10. The second version of the supplement contained both aegeline and CA and was called OxyElite Pro “Advanced Formula” (“OEP-AF”). Doc. 95 at 10.

As alleged in the Indictment, in the fall of 2013, an outbreak of injuries was reported to be associated with USPlabs’ aegeline-based products after numerous consumers in Hawaii experienced liver-related symptoms, including liver failure. Doc. 95 at 11. Following an inspection by the United States Food and Drug Administration (“FDA”), USPlabs agreed to cease distributing the OEP products, but is alleged to have instead pushed sales as fast as possible. Doc. 95 at 11. The Indictment also alleges that USPlabs issued a press release falsely stating that the ingredients in OEP had been researched and showed no negative liver effects, even though Defendants Geissler and Willson knew that a study had shown such negative side effects. Doc. 95 at 11. Eventually, Geissler instructed that both aegeline and CA be removed from the product going forward. Doc. 95 at 11.

The Indictment contains the following charges<sup>2</sup>:

**Count 1** – *Conspiracy to Commit Wire Fraud* (as to all Defendants except Miles), 18 U.S.C. §§ 1343, 1349; Doc. 95 at 12-17. This count involves Defendants’ alleged use of false shipping labels, false COAs, and false shipping documentation to support misleading product labeling in relation to statements that the respective supplements contained “natural” DMAA derived from geranium and CA “extract” (as opposed to CA “root”).

**Counts 2-5** – *Wire Fraud*, 18 U.S.C. § 1343 (as to all Defendants except Miles); Doc. 95 at 18-19. These counts involve Defendants’ alleged transmission in interstate

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Packaging, Labeling, or Holding Operations for Dietary Supplements, 2010 WL 5574459, at \*9 (Dec. 1, 2010).

<sup>2</sup> The Indictment spells out the number of each count rather than using Arabic numerals, for example, “Count One,” instead of “Count 1.” The parties sometimes refer to the counts with Arabic numerals and other times spell out the number of each count. For purposes of consistency, the court will use Arabic numerals when referring to the counts in the Indictment, except when quoting the exact title of a motion.

commerce, by means of wire communications and writing, of false and fraudulent COAs, instructions to create false documents, and other fraudulent statements contained in e-mails.

**Count 6** – *Obstruction of an Agency Proceeding* (as to Defendants USPlabs, Geissler, Doyle, and Hebert only), 18 U.S.C. §§ 2, 1505; Doc. 95 at 20-21. This count charges that, during the FDA investigation regarding whether an outbreak of liver injuries was associated with USPlabs’ products containing aegeline, Defendants USPlabs, Geissler, Doyle, and Hebert continued to distribute OEP products despite representing to the FDA that they would cease distribution, and attempted to impede the FDA’s investigation by failing to provide material information about OEP, the anticipated shipments of OEP, and promotional activities for OEP.

**Count 7** – *Conspiracy to Introduce Misbranded Food into Interstate Commerce with an Intent to Defraud and Mislead*, 18 U.S.C. § 371; 21 U.S.C. §§ 331(a), 333(a)(2) (as to all Defendants except Miles); Doc. 95 at 22-24. This count alleges that certain Defendants conspired to avoid law enforcement attention and match imported substances with false product labeling by instructing Chinese chemical sellers to falsely label numerous chemical powders they sent to USP, including “geranium flower powder extract” and CA root “extract.”

**Count 8** – *Introduction of Adulterated Food into Interstate Commerce with an Intent to Defraud and Mislead* (as to Defendants USPlabs and Geissler only), 21 U.S.C. §§ 331(a), 333(a)(2); 18 U.S.C. § 2; Doc. 95 at 25. This count alleges that Defendants USPlabs and Geissler, aiding and abetting each other, with the intent to defraud and mislead, caused the shipment of misbranded OEP-AF in interstate commerce by using a label falsely declaring that CA “extract” was an ingredient, even though it was not contained in the product.

**Count 9** – *Introduction of Misbranded Food into Interstate Commerce* (as to Defendants Doyle, Hebert, Miles, S.K. Labs, and Patel only), 21 U.S.C. §§ 331(a), 333(a)(2); Doc. 95 at 26. This count alleges that Defendants Doyle, Hebert, Miles, S.K. Labs, and Patel caused the shipment of misbranded OEP-AF in interstate commerce when the food was misbranded under the Food Drug and Cosmetic Act (“FDCA”) by using a false label declaring that CA “extract” was an ingredient, even though it was not contained in the product.

**Count 10** – *Introduction of Adulterated Dietary Supplement into Interstate Commerce*, 21 U.S.C. §§ 331(a), 333(a)(1), and 342(f)(1)(A)(I) (as to all Defendants except Willson); Doc 95 at 27. This count alleges that Defendants caused the shipment of adulterated OEP-NF in interstate commerce, as the supplement “presented a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling.”

**Count 11 - Conspiracy to Commit Money Laundering** (as to Defendants USPlabs, Geissler, Doyle, and Hebert only), 18 U.S.C. § 1956(h); Doc. 95 at 28-29. This count alleges that Defendants USPlabs, Geissler, Doyle, and Hebert conspired to transfer over \$230,000,000 of proceeds obtained through wire fraud and conspiracy in a manner designed to conceal the true source and nature of the criminally derived funds.

**C. Defendants' Motions to Dismiss Referred to Magistrate Judge Toliver**

Responding to the Indictment, Defendants filed Defendants' Motions to Dismiss. *See* Docs. 220, 221, 293, 379, 383, 387, 392, and 394. As previously explained, the court referred Defendants' Motions to Dismiss to Magistrate Judge Toliver for findings and recommendation. On May 10, 2018, she held a hearing on Defendants' Motions to Dismiss. On June 13, 2018, she submitted her Report in which she recommends that all pending Motions to Dismiss be denied, with the exception of Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Cyril Willson's Motion to Dismiss Count 7, which she recommends granting.

**D. Objections to Magistrate Judge Toliver's Report**

On June 25, 2018, Defendants filed the following objections to Magistrate Judge Toliver's Report: Defendants' Joint Objection to the Magistrate Judge's Order on Motion to Dismiss Count 6 (Doc. 480); Defendants' Objections to the Amended Findings, Conclusions, and Recommendation of the United States Magistrate Judge Related to Defendants' Motion to Dismiss Counts Two Through Four (Doc. 482); Defendants' Joint Objection to Magistrate Judge Toliver's Order Denying Defendants' Motion to Dismiss Counts 9 and 10 of the Superseding Indictment (Doc. 483); and Defendants' Objection to Magistrate Judge's Order with Respect to Defendants' Motion to Dismiss Count Ten (Doc. 485). On June 27, 2018, Defendants filed Defendants' Objections to the Magistrate Judge's Amended Findings, Conclusions, and Recommendation with Respect to Defendants'

Motions to Dismiss Counts 5, 8, and 9 (Doc. 488). On July 16, 2018, the Government filed responses to Defendants' objections to Magistrate Judge Toliver's Report. *See* Docs. 496, 497, 499, 500, 502.

On June 25, 2018, the Government filed its objection to Magistrate Toliver's Report insofar as she recommending granting Defendants' motion to dismiss Count 7. *See* Doc. 478. On July 16, 2018, Defendants filed their response to the Government's objection. *See* Doc. 504.

## **II. Legal Standard**

Pursuant to Federal Rule of Criminal Procedure 59(b) and 28 U.S.C. § 636(b)(1), a district court, on its own motion, may refer a pending dispositive matter to a United States Magistrate Judge for findings of fact and recommendation. Fed. R. Crim. P. 59(b)(1); 28 U.S.C. § 636(b)(1). The non-prevailing party may contest the magistrate judge's findings and recommendation by filing written objections within fourteen days of being served with a copy of the findings and recommendation. Fed. R. Crim. P. 59(b)(2). The objections must specifically identify those findings or recommendations the party wishes to have a district court consider. *Id.* A district court must "make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made." 28 U.S.C. § 636(b)(1). It may then "accept, reject, or modify the recommendation, receive further evidence, or resubmit the matter to the magistrate judge with instructions." Fed. R. Crim. P. 59(b)(3); *see also* 28 U.S.C. § 636(b)(1). Failure of a party to file written objections to the magistrate judge's proposed findings and recommendation within fourteen days, or such other time set by the district judge, waives that party's right to judicial review. Fed. R. Crim. P. 59(b)(2).

As Defendants and the Government have filed their objections in a timely manner, the court will review de novo the portions of Magistrate Judge Toliver's Report to which the parties have objected. Because the parties are only entitled to a de novo review of those portions of the Report to which objection is made, the court will review the remainder of the Report under a clearly erroneous standard of review.

### **III. Analysis**

#### **A. Legal Principles Pertaining to Indictments**

Defendants' Motions to Dismiss include challenges to the specificity and sufficiency of the Indictment as it relates to several of the 11 counts. Accordingly, prior to addressing the Magistrate Judge's Report and the parties' objections and responses to the objections, the court reviews the relevant legal principles.

The United States Constitution states that a criminal defendant cannot "be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury," U.S. Const. amend. V, and that he has "the right . . . to be informed of the nature and cause of the accusation[.]" U.S. Const. amend. VI. In keeping with these constitutional principles, Federal Rule of Criminal Procedure 7(c)(1) provides that an indictment "must be a plain, concise, and definite written statement of the essential facts constituting the offense charged and must be signed by an attorney for the government." In each count, the indictment "must give the official or customary citation of the statute, rule, regulation, or other provision of law that the defendant is alleged to have violated." *Id.* "A count may allege that the means by which the defendant committed the offense are unknown or that the defendant committed it by one or more specified means." *Id.* When

applying this standard, common sense should prevail over technicalities. *See* 1 The Late Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 123, at 522–23 (4th ed. 2008).

“The purpose of an indictment is ‘to allege each essential element of the offense charged so as to enable the accused to prepare his defense and to allow the accused to invoke the double jeopardy clause in any subsequent proceeding.’” *United States v. Lawrence*, 727 F.3d 386, 397 (5th Cir. 2013) (quoting *United States v. Morrow*, 177 F.3d 272, 296 (5th Cir. 1999)). “Thus, an indictment is sufficient if it ‘contains the elements of the offense charged and fairly informs the defendant of the charge against which he must defend.’” *Id.* (citation omitted). “It is not necessary for an indictment to go further and to allege in detail the factual proof that will be relied upon to support the charges.” *United States v. Crippen*, 579 F.2d 340, 342 (5th Cir. 1978) (citations omitted). “Generally, an indictment [that] follows the language of the statute under which it is brought is sufficient to give a defendant notice of the crime of which he is charged.” *United States v. Thomas*, 348 F.3d 78, 82 (5th Cir. 2003) (internal quotation marks and citations omitted); *see also United States v. Massey*, 849 F.3d 262, 264 (5th Cir. 2017) (same).

When the court decides a motion to dismiss the indictment for failure to state an offense, it is required to “‘take the allegations of the indictment as true and to determine whether an offense has been stated.’” *United States v. Kay*, 359 F.3d 738, 742 (5th Cir. 2004) (quoting *United States v. Hogue*, 132 F.3d 1087, 1089 (5th Cir. 1998)). A court must deny a motion to dismiss if the motion relies on disputed facts. *See, e.g., United States v. Covington*, 395 U.S. 57, 60 (1969) (holding that a court can resolve a pretrial motion to dismiss the indictment only when “trial of the facts surrounding the commission of the alleged offense would be of no assistance in determining the validity of the defense”); *United States v. Fontenot*, 665 F.3d 640, 644 (5th Cir. 2011) (“The

propriety of granting a motion to dismiss an indictment . . . by pretrial motion is by-and-large contingent upon whether the infirmity in the prosecution is essentially one of law or involves determinations of fact. . . . If a question of law is involved, then consideration of the motion is generally proper.”) (citation omitted).

## **B. The Parties’ Objections**

As previously stated, in her Report, Magistrate Judge Toliver recommended that all pending Motions to Dismiss be denied, with the exception of Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Cyril Willson’s Motion to Dismiss Count 7, which she recommended granting. The parties filed their objections and responses to those objections. The court first addresses Defendants’ objections to the Report.

### *1. Defendants’ Objections to the Magistrate Judge’s Recommendation that the Court deny the Motions to Dismiss Counts 2, 3, 4, 5, 6, 8, 9, and 10*

In accordance with 28 U.S.C. § 636(b)(1), the court has conducted a de novo review of the Report, audio transcript of the May 10, 2018 hearing before Magistrate Judge Toliver, underlying motions, responses, and replies, as well as the Defendants’ objections and the Government’s responses to Defendants’ objections, and applied the pertinent legal principles governing sufficiency of indictments previously discussed. For the most part, Defendants’ Motions to Dismiss address the specificity and sufficiency of the Indictment as it relates to Counts 2 through 10. In addition, Defendants challenge several counts of the Indictment as unconstitutionally vague and challenge Counts 2 through 4 as untimely. With respect to Counts 2, 3, 4, 5, 6, 8, 9, and 10, in recommending that the court deny Defendants’ Motions to Dismiss, Magistrate Judge Toliver has provided the court with a thorough analysis of all of the issues raised by Defendants. As Defendants’ objections

essentially reassert the same arguments made in their underlying motions and replies, and each is addressed by Magistrate Judge Toliver in her well-reasoned thirty-five page Report, the court **concludes** that Magistrate Judge Toliver's legal analysis is correct with respect to recommending that the court deny Defendants' Motions to Dismiss Counts 2, 3, 4, 5, 6, 8, 9, and 10, and incorporates by reference her legal analysis with respect to these Counts as if fully set forth herein verbatim. Accordingly, the court **overrules** Defendants' Objections to the Magistrate Judge's Report insofar as she recommended denial of Defendants' Motions to Dismiss Counts 2, 3, 4, 5, 6, 8, 9, and 10 of the Indictment.

2. *The Government's Objection to the Magistrate Judge's Report  
Recommending that the Court Grant Defendants' Motion to Dismiss Count  
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The Government has filed an objection to the Magistrate Judge's Report insofar as she recommends that the court grant Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Cyril Willson's Motion to Dismiss Count 7. After conducting a de novo review of the Report, audio transcript of the May 10, 2018 hearing before Magistrate Judge Toliver, underlying motions, responses, and replies, as well as the Government's objection, and Defendants' response to the objection, in accordance with the pertinent legal principles governing sufficiency of indictments previously discussed, the court **sustains** the Government's objection.

Count 7 of the Indictment charges all Defendants except Miles with Conspiracy to Introduce Misbranded Food into Interstate Commerce with an Intent to Defraud and Mislead in violation of 21 U.S.C. §§ 331(a) and 377(a)(2). *See* Doc. 95 at 22-24; *see also* 21 U.S.C. §§ 331(a) (prohibiting the introduction of or delivery for introduction into interstate commerce of any misbranded food) and

333(a)(1) (imposing felony-level punishment for violations of § 331(a) when done “with intent to defraud or mislead”). The Indictment alleges the following overt acts committed in furtherance of that object:

61. On or about September 28, 2010, Sitesh Patel and S.K. Laboratories received documentation for a shipment of 1,000 kilograms of “Geranium Flower (HG) Powder Extract” that was scheduled to arrive at S.K. Laboratories in California after having shipped from Texas. Sitesh Patel and S.K. Laboratories knew that the labeling of the shipment was false because the substance in the shipment was not Geranium Flower Powder Extract, but was instead DMAA, a synthetic stimulant.

62. On or about December 8, 2011, Jacobo Geissler instructed a Chinese chemical seller via email to misbrand a shipment of nine different chemicals [ ] sent from China to USP Labs in Texas by writing: “Please send as Green coffee samples and send them all together. . . . And don’t label the individual bags. Label as green coffee sample 1, 2, 3 etc.”

63. On or about June 15, 2013, Jacobo Geissler agreed with a Chinese chemical seller to have two metric tons of ground cynanchum auriculatum root powder shipped internationally to S.K. Laboratories in California, for inclusion in USP Labs’ products, using the false name “cynanchum auriculatum root extract.”

Doc. 95 at 23-24. Further, as alleged in the Indictment, the false documents included: false COAs, upon which dietary supplement retailers and wholesalers rely to verify product ingredients (*id.* at 4, 5, 7, 9-11); and false “labels” identifying ingredients as “green coffee samples.” *Id.* at 9.

Defendants contend that Count 7 of the Indictment should be dismissed because: (1) the documents at issue do not fall within the definition of “labeling”; (2) the Indictment does not allege facts establishing that the allegedly false and misleading “labeling” was material (argued in the alternative); and (3) the FDCA’s definition of “labeling” is unconstitutionally vague (also argued in the alternative). Magistrate Judge Toliver did not reach Defendants’ two alternative arguments, as she agreed in large part with their first argument, which she made the basis of her recommendation that the court dismiss Count 7 of the Indictment.

a. *Labeling Under the FDCA*

In support of their argument that Count 7 should be dismissed, Defendants argue that the term “labeling” only applies to those written materials that provide information about the product to the *ultimate consumers* whom the FDCA is designed to protect. They contend that they did not violate the statute because the documents supporting Count 7 were not directed to the ultimate consumer but instead to USPlabs and S.K. Labs. Second, Defendants urge that the written materials at issue did not constitute labels because they did not provide “substantial information” about the ingredients as articulated by this court and as affirmed by the Fifth Circuit. *See United States v. Hanafy*, 124 F. Supp. 2d 1016, 1018 (N.D. Tex. 2000), *aff’d*, 302 F.3d 485, 490 (5th Cir. 2002).

i. *End-User Restriction*

Magistrate Judge Toliver rejected Defendants’ argument for an end-user restriction on labeling, reasoning:

The purpose of the FDCA is “to safeguard the consumer by applying [it] to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer.” *United States v. Sullivan*, 332 U.S. 689, 696 (1948). The Indictment alleges that the false documentation that accompanied the shipments of the supplement ingredients constituted labels. Doc. 95 at 23-24. Section 321(m) plainly states that the term “labeling” includes “all labels and *other written, printed, or graphic matter* (1) upon any article or any of its containers or wrappers, or (2) *accompanying such article*.” 21 U.S.C. § 321(m) (emphasis added). Thus, putting aside the definition of the term “label,” section 321 also prohibits “other [false] written, printed, or graphic matter” from accompanying food “articles.” Count 7 alleges that falsified documents accompanied the three shipments in question. Such documentation is “labeling” within the meaning of the FDCA.

Report at 27. Neither party has filed an objection to Magistrate Judge Toliver’s rejection of Defendants’ argument for an end-user restriction on the definition of “labeling.” The court agrees with Magistrate Judge Toliver. Defendants’ attempt to impose an end-user restriction on labeling

would lead to results that are at odds with the FDCA's "overriding purpose to protect the public health." *United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969). As noted by the Government: "Under the defendants' interpretation, a person would be permitted to label sawdust as 'wheat flower' and sell it to a bakery for bread production with no fear of being in violation of the FDCA for distributing food with false labeling." Gov't's Resp. to Defs.' Mot. to Dismiss 4 (Doc. 404).

ii. "Substantial Information"

Notwithstanding her rejection of Defendants' proposed end-user restriction on "labeling," Magistrate Judge Toliver went on to agree with Defendants' backup argument, namely, that the written materials at issue do not constitute labels because they did not provide "substantial information" about the ingredients:

Nevertheless, the documentation also must "provide substantial information about the use or benefits of the article," *United States v. Hanafy*, 302 F.3d 485, 490 (5th Cir. 2002), and thereby constitute "an essential supplement to the label attached to the package," *Kordel v. United States*, 335 U.S. 345, 348 (1948). In that light, the *Hanafy* court held that documentation which merely identified the contents of a shipping tray with no more information than that which was already on the articles themselves did not "explain" or provide "substantial information" rising to the level of "labeling." 302 F.3d at 490. While the Government argues that the labels accompanying the food articles at issue constituted "substantial information" to government regulators about the articles, there is no suggestion in the record that the allegedly substantial information explained the use of or benefits of the article as required by *Hanafy* or that Defendants conspired to have it do so.

Rather, it appears from the language of Count 7 that the "labeling" in question constituted Defendants' identifying the articles sent "with no more information than that which [was] already upon the articles themselves." Merely putting a "label" on something - albeit an allegedly false label - that does not "explain" or provide "substantial information" is insufficient and does not rise to the level of "labeling" as contemplated by *Kordel* and *Hanafy*.

Report at 27-28.

The Government objects to this portion of Magistrate Judge Toliver’s Report, contending that Count 7 of the Indictment “sufficiently tracks the statutory language, so the question of whether the documents at issue in this case are ‘labeling’ is a factual one for the jury.” Gov’t’s Obj. 2-3 (Doc. 478). The Government further argues that “even if [it] were required to allege facts in the indictment establishing that the defendants used false ‘labeling,’ [it] has done that here consistent with Fifth Circuit and Supreme Court precedent.” *Id.* at 3. For the reasons that follow, the court will sustain the Government’s objection.

Count 7 charges a conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of the FDCA, closely tracking the statutory charging language, stating specifically that the Defendants conspired to use false and misleading labeling to deliberately misidentify a variety of FDA-regulated chemicals introduced into interstate commerce. Dkt. 95 at 22-24. The Indictment alleges several overt acts in furtherance of the conspiracy and that the object of the conspiracy was “to avoid law enforcement attention.” *Id.* at 22-23.

Under the FDCA, a food is misbranded if “its labeling is false or misleading in any particular . . . .” 21 U.S.C. § 343(a)(1). The term “food” means “articles used for food or drink for man or other animals, . . . and [] articles used for components of any such article.” *Id.* § 321(f). With certain exceptions not relevant to the analysis, “a dietary supplement shall be deemed to be a food [for purposes of the FDCA].” *Id.* § 321(ff). The FDCA defines “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” *Id.* § 321(m). “Label” is defined as “a display of written, printed, or graphic matter upon the immediate container of any article . . . .” *Id.* § 321(k). Thus, a “label” is a subset of “labeling.” In addition, the statute plainly defines “labeling” to encompass written

materials accompanying food ingredients, as Magistrate Judge Toliver correctly noted. *See* Report at 27.

The language in the Indictment is sufficient to charge that the food ingredients were misbranded because their labeling was false or misleading. Count 7 alleges that Defendants shipped ingredients to be used as components of dietary supplements—meaning that they shipped “articles” to be used as “components” of “food”—which the FDCA expressly defines as “food.” *See* Doc. 95 at 22-23; 21 U.S.C. § 321(f). The Indictment further alleges that those ingredients were shipped “with false labeling.” Doc. 95 at 22-23. This means that the “food” Defendants shipped and caused to be shipped had “labeling” that was “false,” which rendered it misbranded under 21 U.S.C. § 343(a)(1).

The court concludes that Count 7, a conspiracy charge, is sufficient because it contains the elements of the offense charged and fairly informs the defendants of the charge against which they must defend. *See generally Lawrence*, 727 F.3d at 397 (“Thus, an indictment is sufficient if it contains the elements of the offense charged and fairly informs the defendant of the charge against which he must defend.”) (citation and internal citation marks omitted); *Thomas*, 348 F.3d at 82 (“Generally, an indictment which follows the language of the statute under which it is brought is sufficient to give a defendant notice of the crime of which he is charged.”) (internal quotation marks and citations omitted); Fed. R. Crim. P. 7(c)(1).

Moreover, even were the Government required to allege facts in the Indictment establishing that Defendants used false “labeling,” as suggested by Magistrate Judge Toliver, contrary to her Report, Count 7 of the Indictment includes specific examples of materials that, if proved, meet the standard for “labeling” in the Fifth Circuit. *See United States v. Hanafy*, 124 F. Supp. 2d 1016 (N.D.

Tex. 2000) (Lindsay, J.) (“*Hanafy I*”), *aff’d*, *United States v. Hanafy*, 302 F.3d 485 (5th Cir. 2002) (“*Hanafy II*”). In *Hanafy II*, the Fifth Circuit affirmed this court’s holding that shipping trays used to hold baby formula containers did not constitute labeling under the FDCA. *Hanafy II*, 302 F.3d at 490. The defendants in that case consolidated genuine cans of baby formula from the manufacturer into shipping trays that were designed to extend upward only a few inches so that the genuine cans would remain visible. *Id.* at 486. The Government in that case argued that the shipping trays used by defendants constituted labeling for the baby formula that was false or misleading and offered evidence that the shipping trays resembled the manufacturers’ trays but failed to reveal that the baby formula containers were repackaged into the defendants’ trays. *Id.* The Fifth Circuit, affirming this court, explained that the trays were not labeling because they did not “explain” or “provide” “substantial information” about the use or benefits of the baby formula beyond the correct, visible labels on the baby formula containers themselves. *Id.* at 490; *see also Hanafy I*, 124 F. Supp. 2d at 1027 (“[T]he *only* information that apparently would be gleaned from the shipping trays would be that the product had been repacked.”) (original emphasis).

Unlike the shipping trays in *Hanafy* that did not “explain” or “provide” “substantial information” beyond “that which [was] already upon the articles themselves,” *Hanafy II*, 302 F.3d at 490, the Indictment in this case alleges that labeling—including labels on the articles themselves—fraudulently misidentified contained ingredients. Also unlike the Indictment in *Hanafy*, in which the Government alleged that the misbranded material duplicated a lawful label or simply failed to reveal additional information, here, the Indictment alleges that Defendants conspired to use affirmatively false “labels” and other affirmatively false “labeling” that, among other things, misidentified the actual articles of food. Doc. 95 at 6-11. For example, the Government has alleged

that Geissler instructed a Chinese chemical seller to hide the names of chemicals to be shipped from China to Texas “by writing: ‘Please send as Green coffee samples and send them all together . . . . And don’t label the individual bags. Label as green coffee sample 1, 2, 3 etc.’” *Id.* at 15. The Indictment also alleges that “USP Labs sent false labels listing ‘cynanchum auriculatum (root) extract’ as an ingredient in OxyElite Pro Advanced Formula to retailers and wholesalers, even though that ingredient was not present in the product.” *Id.* False labels bearing the wrong product name are “labeling” under the FDCA because they convey substantial information about the contents of the container. As the Government persuasively argued in its objection to the Report: “Accepting the recommendation to dismiss Count 7 would mean that, for instance, Viagra labeled as Tylenol would not be misbranded under the FDCA. *Hanafy* did not hold or even suggest that dangerous substances can be fraudulently labeled as safe substances with no consequences.” Gov’t’s Obj. 6 (Doc. 478).

In addition to actual labels on the products themselves, the court agrees with the Government that the COAs referred to in the Indictment also explain and convey “substantial information” about the product. Paragraph 16 of the Indictment alleges that a COA provides information to a manufacturer “certifying that the ingredient listed in the COA ha[s] been tested or otherwise evaluated, . . . [is] what it purport[s] to be . . . and [does] not contain dangerous levels of mercury or other toxic substances.” Doc. 95 at 4. Paragraph 18 of the Indictment alleges that retailers rely on representations contained in “product labeling and in COAs” to determine that products are lawful to sell and contain what they purport to contain. *Id.* at 5. Paragraph 24 of the Indictment alleges that one COA at issue falsely portrayed a chemical it imported as “having been extracted from ‘geranium flower powder’ . . . using a ‘hydro-alcoholic’ extraction process at a 200-to-1 ratio.”

*Id.* at 7. These COAs “supplement[] or explain[]” the product, as they undoubtedly inform the customer about the quality and purity of an ingredient. *See Kordel v. United States*, 335 U.S. 345, 348, 350 (1948) (literature “supplement[ing] or explain[ing]” the use of drugs, even when shipped separately, constituted “labeling” under the FDCA (*id.* at 350); the drugs and literature were “interdependent,” having a “common origin and common destination,” and the literature “constituted an essential supplement to the label attached to the package” (*id.* at 348)). Finally, Count 7 alleges that the false labeling included such COAs as well as other false labeling. Doc. 95 at 22-24. The court concludes that these labels and COAs are what the recommendation to dismiss Count 7 erroneously states are missing from the Indictment.

In sum, to the extent Magistrate Judge Toliver required the Government to provide further factual support in the Indictment concerning “labeling,” the court **sustains** the Government’s objection and **rejects** her Report and its recommendation that Count 7 be dismissed on this basis. Whether the written materials the Government might present at trial in support of Count 7 qualify as “labeling” is a factual determination, and not an appropriate inquiry at the motion-to-dismiss stage. *See Fontenot*, 665 F3d at 644 (“The propriety of granting a motion to dismiss an indictment . . . by pretrial motion is by-and-large contingent upon whether the infirmity in the prosecution is essentially one of law or involves determinations of fact . . . . If a question of law is involved, then consideration of the motion is generally proper.”) (citation omitted). Also buttressing the court’s conclusion is that Count 7 is a conspiracy charge. *See Lawrence*, 727 F.3d at 397 (“It is well established that in an indictment for conspiring to commit an offense—in which the conspiracy is the gist of the crime—it is not necessary to allege with technical precision all the elements essential to the commission of the offense [that] is the object of the conspiracy.”) (internal quotation marks

and citation omitted). Further, even were the Government required to detail in the Indictment how the written materials at issue constituted “labels” and “labeling,” the Government has done so here with its allegations of actual false labels on the products themselves and COAs, both of which were allegedly intended to explain and provide “substantial information” about the products. *See Kordel, supra; Hanafy II, supra.*

*b. Defendants’ Alternative Arguments in Support of Their Motion to Dismiss Count 7 of the Indictment*

Magistrate Judge Toliver’s recommendation that the court grant Defendants’ motion to dismiss Count 7 was based on her acceptance of Defendants’ first argument in support of dismissal, obviating the need for her to Defendants’ two alternative arguments in support of their motion to dismiss Count 7, namely, that the Indictment does not allege facts establishing that the allegedly false and misleading “labeling” was material; and that the FDCA’s definition of “labeling” is unconstitutionally vague. As this court has sustained the Government’s objection to Magistrate Judge Toliver’s Report with respect to Count 7, Defendants’ alternative arguments in support of their motion to dismiss Count 7 must now be addressed for the first time.

*i. “Materiality”*

Count 7 of the Indictment alleges that Defendants conspired to introduce misbranded food into interstate commerce “with the intent to defraud and mislead.” Doc. 95 at 22. In support of their motion to dismiss Count 7, Defendants argue that the Government cannot prove they had the intent to defraud or mislead because it has not shown that the false or misleading labeling was material. The Government counters that, even assuming a materiality requirement applies to the FDCA—and

not just mail, wire, and bank fraud statutes—the Indictment is sufficient to permit an inference of materiality.<sup>3</sup>

A fraud indictment need not specifically state that a lie or misrepresentation was material, as long as the facts alleged permit an inference of materiality. *United States v. Caldwell*, 302 F.3d 399, 409 (5th Cir. 2002) (“If the facts alleged in the indictment warrant an inference of materiality, the indictment is not fatally insufficient for its failure to allege materiality in haec verba.”); *United States v. Bieganowski*, 313 F.3d 264, 286 (5th Cir. 2002) (same); *United States v. McGough*, 510 F.2d 598, 603 (5th Cir. 1975) (same).

First, the court assumes, without finding, that the Government must prove “materiality” to establish an intent to violate the FDCA with the “intent to defraud or mislead.” *But see supra note* 3. The court need not decide this issue, however, as it finds that the Indictment supplies all the elements required to state a substantive offense in Count 7. Among other things, the Indictment alleges that Defendants attempted to mislead government agencies by using false labeling to import ingredients, and that they also used the false ingredient labeling to match label claims on the finished products. Doc. 95 at 22-23. The allegations in the Indictment are more than sufficient for the court to infer that the mislabeling of ingredients for shipment was material to FDA examiners. *See Gov’t’s*

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<sup>3</sup> Defendants support their argument that the Government must prove materiality to establish a violation of the FDCA with the “intent to defraud or mislead” by citing to *Neder v. United States*, 527 U.S. 1 (1999) and *United States v. Watkins*, 278 F.3d 961 (9th Cir. 2002). In *Neder*, the Supreme Court analyzed whether a “scheme or artifice to defraud” required materiality. 527 U.S. 1. The Court held that it did, reasoning that when Congress enacted the mail fraud, wire fraud, and bank fraud statutes, “fraud” had a well-settled meaning at common law that required materiality. *Id.* In *Watkins*, the Ninth Circuit followed the logic of *Neder* in extending the materiality requirement to the “intent to defraud” and the “intent to mislead” under the FDCA. 278 F.3d 961. In response to Defendants’ motion to dismiss Count 7, the Government states that it is not aware that any other circuit has extended the materiality requirement to the FDCA. *See Gov’t’s Resp. 7 n.3* (Doc. 404). The court’s independent research also leads it to the same conclusion.

Resp. 7-8 ( “[I]t is obvious that when a party purposefully imports an ingredient using the wrong name, then lies about the identity of the ingredient in the finished product, these lies would have the natural effect of influencing, for example, FDA import examiners and consumer purchasers.”); *Neder v. United States*, 527 U.S. 1, 16 (1999) (statement is material “if it has a natural tendency to influence, or is capable of influencing, the decision of the decision-making body to which it was addressed.”).<sup>4</sup>

Accordingly, the court rejects Defendants’ motion to dismiss Count 7 on this basis.

*ii. Vagueness Challenge*

Defendants alternatively argue that the FDCA’s definition of “labeling” is vague and ambiguous in violation of the Fifth Amendment’s Due Process Clause. Defendants contend they “were not given prior fair notice that ordering compounds from an overseas supplier under inaccurate Customs-related import documentation could trigger criminal liability for misbranding.” Defs.’ Mot. to Dismiss Count 7 10 (Doc. 379). According to Defendants, “the FDCA’s definition of labeling, after almost 70 years of jurisprudence, should be construed to exclude the type of documentation at issue in Count 7.” *Id.* at 10-11. The Government counters that “there is nothing ambiguous or constitutionally vague about the statutory terms or the charges in the Indictment.” Gov’t’s Resp. 9 (Doc. 404).

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<sup>4</sup> The court is not persuaded by Defendants’ additional argument that any alleged false and misleading labeling to the Government about the identity of these ingredient shipments were not material because the Government would have let the shipments into the country in any event. As the Government correctly notes: “Even if that were true, which it is not, it has nothing to do with whether the allegations in the indictment are sufficient to permit an inference of materiality. In any event, whether the statements were actually material is a matter for the fact-finder to determine at trial.” Gov’t’s Resp. 8 (Doc. 404).

When a defendant challenges a criminal statute as vague, courts consider the challenge under the rubric of the Fifth Amendment's due process clause. *Johnson v. United States*, \_\_ U.S. \_\_, 135 S. Ct. 2551, 2556-57 (2015). The Government violates due process by taking away an individual's "life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." *Id.* at 2556 (citation omitted). A statutory provision is facially vague when it is plagued with such "hopeless indeterminacy" that it precludes "fair notice of the conduct it punishes." *Id.* at 2556-58. A facially vague provision is "so standardless that it invites arbitrary enforcement." *City of El Cenizo, Texas v. Texas*, 890 F.3d 164, 190 (5th Cir. 2018) (quoting *Johnson*, 135 S. Ct. at 2556); *see also id.* (citing *Coates v. City of Cincinnati*, 402 U.S. 611, 616 (1971) (finding an ordinance facially vague because it proscribed "annoying" conduct)). Defendants have not established that "labeling" is facially vague under this exacting standard.

As pointed out by the Government, the Seventh Circuit rejected this exact vagueness challenge in the case of a medical device vendor who argued that he could not have known that the documents he forged would be considered "labeling." *United States v. Walton*, 36 F.3d 32, 35 (7th Cir. 1994).<sup>5</sup> The appellate court found that "[t]he statute is not vague, and, in fact, it is more easily

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<sup>5</sup> The defendant in *Walton* challenged the Anti-Tampering Act (the "Act"), under which he was convicted, as unconstitutionally vague. *United States v. Walton*, 36 F.3d 32, 34 (7th Cir. 1994). The Act imposes criminal penalties on anyone who "with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or the *labeling* of, or container for, any such product." 18 U.S.C. § 1365(a) (emphasis added). The Act explicitly adopts the definition of "labeling" used in the Food, Drug and Cosmetic Act at section 321(m), the same language Defendants are challenging in this case, and which defines "labeling" to mean "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying the article." *Id.* § 1365(h)(2).

comprehended than many others.” *Id.* The court agrees with the Seventh Circuit’s reasoning and, accordingly, rejects Defendants’ vagueness challenge. A person of reasonable intelligence, considering the statutory language, *see supra*, would readily understand that changing the labels of food and food ingredient shipments, and creating false COAs (*see supra* note 1), with an intent to defraud or mislead the Government (or anyone else), is illegal under the FDCA.<sup>6</sup>

Also in this vein, the court rejects Defendants’ subsidiary argument that it should invoke the “rule of lenity” to resolve ambiguity in the term “labeling.” “[T]he rule of lenity only applies if, after considering text, structure, history, and purpose, there remains a grievous ambiguity or uncertainty in the statute such that the Court must simply guess as to what Congress intended.” *Marachich v. Spears*, 570 U.S. 48, 76 (2013); *see also Muscarello v. United States*, 524 U.S. 125, 138 (1998) (“The simple existence of some statutory ambiguity, however, is not sufficient to warrant application of [the rule of lenity], for most statutes are ambiguous to some degree.”). Defendants have not established a “grievous ambiguity or uncertainty” requiring the court to guess what Congress intended. Absent this type of ambiguity, application of the rule of lenity is unwarranted.

Accordingly, the court will deny Defendants’ motion to dismiss Count 7 on this basis.

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<sup>6</sup> Insofar as Defendants are making a vagueness challenge to the FDCA’s definition of “labeling” as applied in this case, the allegations in the Indictment, which the court must take as true on a motion to dismiss, *see United States v. Fontenot*, 665 F.3d 640, 644 (5th Cir. 2011), suggest that Defendants understood that FDA scrutiny could be avoided by inaccurate ingredient labeling. Count 7 includes an allegation that Geissler instructed a Chinese chemical seller via e-mail to misbrand a shipment of nine different chemicals sent from China to USPlabs in Texas by writing: “Please send as Green coffee samples and send them all together. . . . And don’t label the individual bags. Label as green coffee sample 1, 2, 3 etc.” Doc. 95 at 24. The Indictment also alleges that Geissler was concerned about importing large amounts of DMAA, which he referred to as a “questionable powder,” and told Patel that the “last thing” he wanted was for USPlabs to be “on the FDA radar.” *Id.* at 6.

#### IV. Conclusion

For the reasons herein stated, it is hereby **ordered** that Defendants' Objections to Magistrate Judge Toliver's Report (*see* Docs. 480, 482, 483, 485, and 488) are **overruled** in their entirety, and the Government's Objection to Magistrate Judge Toliver's Report is **sustained**. Accordingly, the court hereby **accepts in part** and **rejects in part** Magistrate Judge Toliver's Report as the Opinion and Order of this court. The court **accepts** Magistrate Judge Toliver's Report insofar as she recommends that the court deny Defendants' Motion to Dismiss Counts 2, 3, 4, 5, 6, 9, and 10 (*see* Docs. 220, 221, 293, 383, 387, 392, 394), and **rejects** her Report insofar as she recommends that the court grant Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Cyril Willson's Motion to Dismiss Count 7 (*see* Doc. 379). The court, therefore, **denies** the following motions:

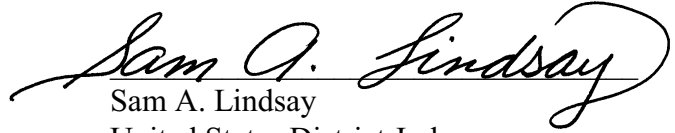
1. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc., and Sitesh Patel's Motion to Dismiss Count Ten (Doc. 220);
2. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles' Motion to Dismiss Counts Nine and Ten for Unconstitutional Vagueness (Doc. 221);
3. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Counts Two Through Four of the First Superseding Indictment as Untimely (Doc. 293);
4. Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Cyril Willson's Motion to Dismiss Count 7 (Doc. 379);
5. Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles' Joint Motion to Dismiss Counts 5, 8, and 9 (Doc. 383);

6. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Count 6 (Doc. 387);

7. Defendant Kenneth Miles' Motion to Dismiss Count Nine and Ten (Doc. 392); and

8. Defendant Cyril Willson's Motion to Dismiss Count 5 and Motion to Adopt In-Part Codefendants' Motion to Dismiss Counts 5, 8, 9 (Doc. 394).

**It is so ordered** this 5th day of October, 2018.

  
Sam A. Lindsay  
United States District Judge